REMARKS

This response is submitted in reply to the Office Action mailed November 27, 2009 ("the Action"). Claims 1-13, 15-23, 34 and 41-47 are pending but stand rejected. Claims 14, 24-33 and 35-40 were canceled in a Preliminary Amendment in anticipation of a restriction to reduce filing fees. New Claims 48-57 have been added that correspond to one or more of these original claims (alone or combined with features from other original claims) as the claim set was not restricted.

I. The Withdrawal of the Prior §103 Rejections

Applicant acknowledges, with appreciation, the withdrawal of the prior obviousness rejections of Claims 1, 4, 8-9, 11-12, and 19 over U.S. 2002/0193685 to Mate et al. ("Mate") in view of U.S. Patent No. 5,142,930 to Allen et al. ("Allen 1") or in further view of WO 97/33513 to Iddan ("Iddan").

II. The New Art Rejections

The Action now rejects the pending claims (Claims 1-13, 15-23, 34 and 41-47) as being obvious over Mate in view of a different "Allen" patent, U.S. 4,945,914 to Allen ("Allen") and in further view of WO/97/33513 to Knapp ("Knapp").

More particularly, the Action states that Mate teaches a target locating an *in vivo* sensor system used with a therapy delivery and imaging source, an external solenoid and at least one implantable wireless unit with a solenoid that generates a coupling signal that varies based on the position of the external solenoid relative to the implanted unit. Applicant respectfully disagrees. Mate proposes a fixed (static) array of sensors 34 on the exterior of the body.

The Action concedes that Mate does not teach a mechanism configured to controllably move the (external) solenoid and a controller which directs the movement of the mechanism. However, the Action states that Allen teaches these features (citing to col. 15, lines 12-27) and alleges that one of skill in the art would have found it obvious to modify Mate to include

a mechanism to control movement of the solenoid per Allen "because with the robot mechanical arm and sensor/solenoid at its tip [the] surgeon can effectively keep track of the solenoid/fiducial implant inside the body." (Action, p. 4). Knapp is cited for teaching communication with the implanted sensor unit using a bit encoded RF signal (citing Abstract, p. 3, lines 1-33). Applicant respectfully disagrees.

Notably, Mate proposes a Guided Radiation Therapy System with an internal marker and a computer that controls movement of the patient and a patient support device so that the target isocenter is coincident with the machine isocenter (Abstract). As noted above, Mate proposes a fixed sensor array 34.

Allen proposes at least four fiducial implants in fixed locations (e.g., on the skull) that are detectable by an imaging system (col. 4, lines 5-10 and 63-64). Allen states that the invention ensures that scans taken at different times produce images substantially identical to previous scans even using different image modalities (col. 3, lines 27-32). "Intermittently, as part of surgical techniques, scans can be made to determine if the tumor has moved or substantially changed in size as a result of the surgery. The laser or other surgical instrument can be adjusted accordingly." (col. 3, lines 42-46). The fiducial implants define a plane which cooperates with the imager (col. 3, lines 50-55).

Allen does describe the use of a robot arm 34 with a base 36 defining the origin (0, 0, 0) of the external coordinate system B. At the tip 38 of the robot arm 34 is a sensor 40. The sensor 40 can be a metal detector or an ultrasonic detector (or any instrument) that can sense the position of a fiducial implant 10 in a body 32. (col. 15, lines 11-20). The arm has sensors at joints and the system can track the arm so that the tip location of the arm is always known (col. 15, lines 27-34).

Allen does not electrically couple a solenoid on the robotic arm with the fiducial implant(s) to provide *a coupling signal* that is used to determine the position of the implants at all. Indeed, Allen uses images and scan planes and correlates internal and external coordinates systems. Applicant submits that Allen describes that the arm 34 is tracked, but does so based on the location of the tip of the arm. The fiducial implants are used to define an internal coordinate system and are not coupled to the arm sensor 40, and the arm sensor 40

and implants do not cooperate to generate a coupling signal that is used to determine the location of the implant.

> When the tip 38 of the arm 34 rests on implant 10 in the skull 18, the location of the internal coordinates system A defined by fiducial implants 10 is known with respect to the external coordinate system B. Supplying the Euler angels of rotation and the location of the tumor which is known relative to the internal coordinates system A to the computer, provides the ability to determine the location of the tumor in the external coordinate system B.

(col. 15, lines 33-43). Thus, even combined, the cited prior art fails to teach or suggest the claimed coupling signal subject matter.

Clearly, Mate and Allen work in very different ways. Applicant submits that one of skill in the art would not have modified Mate to use the arm of Allen, much less in the manner alleged by the Action, as each works as intended and there is simply no motivation to combine these references in the manner alleged. In addition, if properly combinable, the system of Mate would appear to be modified to use a moving arm with a tip (metal detector/ultrasound) sensor and WITH fixed location fiducial makers that define an internal coordinate system for an image guided system (*see, e.g.*, col. 13, lines 20-30, col. 14, line 50 *et seq.*).

Applicant submits that a reference must be read for its overall teachings. Indeed, it is improper to select isolated features from different patents based on the teachings of the instant application.

Further, Mate proposes a number of ways to identify the location and movement of the marker in the body, *see, e.g.*, the array of markers (Figure 4) without using the claimed technique/mechanism. Thus, there is no need to modify the device of Mate as alleged. Notably, despite the fact that Allen issued in 1990, more than 10 years before the filing date of Mate, Mate fails to teach or suggest the use of a moving arm/mechanism with an external solenoid that couples to the internal solenoid to identify position of the internal sensor/marker.

Applicant submits that the use of a mechanical arm that cooperates with the internal

solenoid/sensor to generate a coupling signal to determine position is very different from the systems proposed by Mate or Allen. For example, embodiments of the present invention determine the location using variations in the detected coupling signal which is dependent on the application of energy from and movement of the external solenoid with respect to the internal sensor/solenoid.

The independent claims are restated below for ease of discussion.

1. A target locating and *in vivo* sensor system adapted for use with a therapy delivery and/or imaging source, comprising:

an external solenoid member;

a mechanism operably associated with the external solenoid member, wherein, in operation, the mechanism is configured to controllably move the solenoid external of a patient;

a controller configured to direct the movement of the mechanism, the controller being in communication with a power source configured to power the external solenoid;

at least one implantable wireless unit comprising a solenoid, wherein, in operation, the unit solenoid held internally in the patient cooperates with the external solenoid to generate a coupling signal having a signal strength that varies based on the position of the external solenoid member relative to the implanted unit; and

a computer module in communication with the controller comprising computer program code that evaluates the coupling signal strength in relation to the position of the external solenoid and determines the position of the at least one internally implanted unit.

23. A method of obtaining spatial data and radiation dose data regarding a target *in vivo* treatment site, comprising:

sensing *in vivo* at least one predetermined parameter of interest in a patient using at least one implanted sensor unit;

wirelessly transmitting data associated with the sensed at least one parameter from the at least one sensor unit to an external reader;

moving an articulating arm about the patient in a three-dimensional pattern, the articulating arm having an associated coupling member located external of the patient proximate the target treatment site, the coupling member being configured to cooperate with the at least one implanted sensor to generate a coupling signal with a signal strength that varies in relation to the position of the coupling member with respect to the at least one sensor unit;

detecting the signal strength of the coupling signal at a plurality of locations traveled based on the moving step; and

determining the position of the at least one sensor unit in the body based on the detecting step, thereby having the implanted sensor unit act as a positional marker and an in vivo sensor.

34. A computer program product for obtaining spatial data regarding the position of at least one implanted sensor, the computer program product comprising:

computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:

computer readable program code for determining the spatial location of a selected one of the at least one implanted sensor units using input data associated with variation in signal strength of a coupling signal generated by an external solenoid and the at least one sensor unit over different known external positions of the external solenoid as the external solenoid moves through a three-dimensional pattern in free space.

Applicant submits that the cited prior art fail to teach or suggest at least the emphasized features, including, *inter alia*, sensing an internal parameter as well as providing spatial data as recited in method Claim 23, and moving the external solenoid in a three-dimensional pattern in free-space per Claim 34. Thus, the claims are patentable for at least the emphasized features and/or the distinctions noted above.

Applicant also submits that the dependent claims are independently patentable over the cited prior art.

A. Claims 6 and 13

With respect to Claims 6 and 13, Applicant submits that neither reference teaches or suggests that the external solenoid and the internal solenoid of the at least one sensor unit are configured to cooperate to generate a detectable coupling signal at a depth of up to at least about 14 cm. Indeed, Allen primarily describes skull mounted fiducial markers.

Applicant submits that Claims 6 and 13 are patentable over the cited prior art.

B Claims 15 and 16

The Action alleges that the "combined" Mate and Allen system performs the functions of Claims 15 and 16 "because the system has to evaluate signal shape and strength coming from internal sensor in order to locate the internal sensor position." Action, p. 4. Applicant respectfully disagrees.

As discussed above, Mate uses a fixed sensor array and Allen uses a mechanical arm with a sensor on its tip, neither uses an external solenoid that generates a coupling signal shape as recited in Claims 15 and 16.

> 15. A system according to Claim 1, wherein the external solenoid generates a signal shape that varies with spatial and angular orientation with the internal solenoid of the sensor unit, and wherein said computer module comprises computer program code that evaluates the detected coupling signal strength and shape and deconvolutes the signal with respect to position to determine the spatial location of the sensor in the subject.
>
> 16. A system according to Claim 15, wherein the controller directs the mechanism to move the solenoid through a three dimensional pattern in free space to generate a corresponding response coupling signal, and wherein the computer module program code that evaluates the coupling signal strength uses the response signal generated by the three dimensional pattern to determine the position of the sensor unit.

Further, Applicant submits that clearly Allen does not teach or suggest moving the mechanism arm through a 3-D pattern in free space to generate the coupling signal (Allen proposes contacting the tip sensor to the fiducial marker). Applicant submits that Claims 15 and 16 are patentable over the cited prior art.

C. Magnetic Coupling Signal

Claims 49, 51 and 57 recite that the coupling signal is a magnetic coupling signal. Applicant also submits that these claims are independently patentable over the cited prior art.

D. Radiation Dose Data

Applicant agrees that implantable radiation sensors are known. *See, e.g.*, U.S. Patent No. 6,402,689. However, it is the claimed combination of features that is the proper focus of review of patentability. Certain of the claims are directed to systems whereby the sensors are configured to provide dose data as well as to cooperate with the external solenoid to generate the coupling signal for position assessment. Applicant respectfully submits that this claimed combination of elements is patentable over the cited art. *See, e.g.*, Claims 11, 19, 23, 50 and the like.

E. Three Dimensional Pattern in Free Space

Applicant submits that the cited prior art fails to teach or suggest moving the articulating arm and solenoid in a three-dimensional pattern in free space to generate the coupling signal. Applicant submits that Claims 3, 16, 34 and 50 are patentable for at least this feature.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on April 9, 2010.

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Cara L. Rose